

Issue Under 35 U.S.C. §102(b)

Claims 1-7, 9 and 11 stand rejected under 35 U.S.C. §102(b) as being clearly anticipated by Posti '354 (USP 5,525,354). Applicants submit that patentable distinctions exist between the cited prior art and the present invention.

Present Invention

Applicants have directed the present invention to a pharmaceutical preparation for oral uses, especially tablet form, that has as its active ingredient a pharmacologically acceptable salt of dichloromethylene bisphosphonic acid and the excipient contains silicified microcrystalline cellulose. A second embodiment is a process for manufacture of the aforementioned pharmaceutical preparation.

Applicants' invention requires silicified microcrystalline cellulose as an excipient, which has better powder flow and compactibility; thus, Applicants' tablet is stronger and smaller, which are advantages over the prior art.

Distinctions Between the Present Invention and Posti '354

Posti '354 discloses a pharmaceutical preparation for oral use containing a pharmacologically acceptable salt of dichloromethylene bisphosphonic acid. Posti '354 discloses that the preparation may contain known carriers and other additives and adjuvants. Of these additives, Posti '354 discloses

microcrystalline cellulose as a filler and colloidal silicon dioxide as a lubricant.

As stated in the previous response, Posti '354 fails to disclose a pharmaceutical preparation containing silicified microcrystalline cellulose. The Examiner is incorrect that Example 1 discloses silicified microcrystalline cellulose.

Applicants have defined silicified microcrystalline cellulose as the product of coprocessing microcrystalline cellulose with silicone dioxide. Posti '354 fails to disclose this material; Posti '354 only discloses that the microcrystalline cellulose and silicon dioxide are added to dry clodronate granules. In Posti '354, the dry mixture is then wetted with a solution of steric acid and ethanol. The Examiner then assumes that silicified microcrystalline cellulose is inherently formed in the mixture. Applicants traverse this assumption.

Applicants have attached a 37 C.F.R. §1.132 Declaration by an inventor of the present invention and Posti '354. Mr. Rantala discusses the fundamental differences between the present invention and the cited prior art. More importantly, Mr. Rantala requested an expert, Dr. Yliruusi, in the area of silicified microcrystalline cellulose (SMCC) to write a letter describing the difference between SMCC and microcrystalline cellulose mixed with colloidal silica (MCC).

Applicants have also attached some of the references discussed by Dr. Yliruusi. Applicants do not believe these

references are relevant to the patentability of the present invention, but they do provide background information as to the SMCC component. However, if the Examiner wishes, Applicants can submit the entire list of references from the Dr. Yliruusi letter in an Information Disclosure Statement.

Consequently, a skilled artisan would understand that SMCC could not be inherently formed as the Examiner has assumed and must be made separately as described in the present disclosure. SMCC is a unique compound and component of the present invention.

Applicants assert that Posti '354 fails to anticipate the present invention. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Since Posti '354 fails to disclose the component SMCC of the present invention, Posti '354 fails to anticipate the present invention.

Applicants respectfully request withdrawal of the 35 U.S.C. §102(b) rejection.

Issue Under 35 U.S.C. §103(a)

Claims 1-9 and 11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Posti '354. Applicants submit the patentable distinctions exist between the cited prior art and the present invention.

Distinctions Between the Present Invention and Posti '354

The Examiner has asserted that Posti' 354 fails to disclose a process of dry granulation. However, the Examiner asserts that a skilled artisan would use dry granulation, because it is well known in the art.

As stated above, Posti '354 fails to disclose or suggest a pharmaceutical preparation containing dichloromethylene bisphosphonic acid, and silicified microcrystalline cellulose. Posti '354 fails to recognize the benefit of using silicified microcrystalline cellulose. As stated above, Posti '354 uses microcrystalline cellulose and silicon dioxide separately, which is a traditional way to form a pharmaceutical preparation, but is fundamentally different from the present invention.

The Examiner has not established any motivation for a skilled artisan to make the present invention by dry granulation. The fact that a dry granulation process is known in the art is not motivation to make a pharmaceutical preparation with unique components by dry granulation.

As stated above, Mr. Rantala discusses the striking differences between the present invention and Posti '354 of which he is intimately knowledgeable. Clearly, the present invention is not obvious over Posti '354.

The Examiner must present a *prima facie* case of obviousness consisting of motivation or suggestion to modify or combine

references such that one of ordinary skill in the art has a reasonable expectation of success of making the present composition. The cited reference fails to disclose or suggest the component SCMM or a dry granulation process as set forth in the claims; thus, a *prima facie* case of obviousness has not been presented.

Therefore, a patentable distinction exists between the present invention and the cited reference. Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection.

Conclusion

Applicants submit for the reasons stated above that the present claims define patentable subject matter such that this application should be placed into condition for allowance.

If the Examiner has any questions regarding the above matters, please contact Applicants' representative, Mark W. Milstead (Reg. No. 45,825), in the Washington, metropolitan area at the telephone number listed below.

Pursuant to 37 C.F.R. 1.17 and 1.136(a), the Applicants respectfully petition for a one (1) month extension of time for filing a response in connection with the present application. The required extension fee of \$110.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any

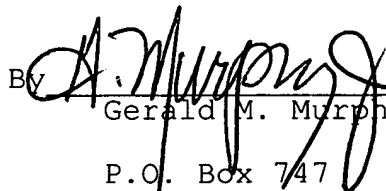
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overpayment to Deposit Account No. 02-2448 for any additional fee required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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By



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